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## STATEMENT BY APPLICANT

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1

of

3

10/010,345

December 5, 2001

A.G. Daifotis

1617

T.J. Criares

20002YIBCA

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]Examiner  
SignatureDate  
Considered

6/25/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## INFORMATION DISCLOSURE

## STATEMENT BY APPLICANT

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## COMPLETELY KNOWN

Application Number	10/010,345
Filing Date	December 5, 2001
First Named Inventor	A.G. Daifotis
Group Art Unit	1617
Examiner Name	T.J. Criares
Attorney Docket Number	20002YIBCA

Sheet 2 of 3

## OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
MC	CI	Men's Osteoporosis Support Group, Vol. 1, Issue 2, 1 July 1997
	CJ	Rote List 1997, 66 023 (Fosamax)
	CK	Reddy M.S. et al, J. Periodontol, 1995, Vol. 66(3), pp. 211-217, "Alendronate Treatment of Naturally-Occurring Periodontitis in Beagle Dogs".
	CL	Fleisch H., "Bisphosphonates in Bone Disease from the Laboratory to the patient", 1995 (Book)
	CM	Black D.M. et al., The Lancet, 1996, 348, pp. 1535-1541, "Randomised trial of effect of alendronate on risk of fracture in women with existing vertebral fractures".
	CN	Affidavit of Gideon Rodan from validity trial of IL 94612 dated 17 Nov. 2000
	CO	Merck & Co., Inc. - Instructions for Once Weekly Fosamax, January 2001
	CP	Lombardi et al., Ann. Ital. Med. Int. 7, 1992, 3 Suppl., pp. 158-165, "Clinical trials with bisphosphonates"
	CQ	Reid et al, American Journal of Medicine, 1996, Vol. 101, pp. 341-348, "Biochemical and Radiologic Improvement in Paget's Disease of Bone Treated with Alendronate: A Randomized, Placebo-controlled Trial".
	CR	Passeri et al, Bone and Mineral, 1991, Vol. 15, pp. 237-248, "Intermittent treatment with intravenous 4-amino-1-hydroxybutylidene-1,1-bisphosphonate (AHBuBP) in the therapy of postmenopausal osteoporosis".
	CS	Devogelaer et al, Bone, 1996, Vol. 18(2), pp. 141-150, "Oral Alendronate Induces Progressive Increases in Bone Mass of the Spine, Hip, and Total Body Over 3 Years in Postmenopausal Women with Osteoporosis".
	CT	Siris et al, J. Clin. Endo. Metab., 1996, Vol. 81(3), pp. 961-967, "Comparative Study of Alendronate Versus Etidronate for the Treatment of Paget's Disease of Bone".
	CU	Toolan et al, J. Bone Min. Res., 1992, Vol. 3, pp. 1399-1406, "Effects of 4-Amino-1-Hydroxybutylidene Bisphosphonate on Bone Biomechanics in Rats".
	CV	Balena et al, Bone, 1993, Vol. 14, pp. 499-504, "the Aminobisphosphonate Alendronate Inhibits Bone Loss Induced by Thyroid Hormone in the Rat Comparison Between Effects on Tibiae and Vertebrae".
	CW	Liberman et al., The New England Journal of Medicine, Vol. 333(22), 1995, p. 1437, "Effect of Oral Alendronate on Bone Mineral Density and the Incidence of Fractures in Postmenopausal Osteoporosis".

Examiner Signature

Date Considered

6/25/04

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